October 8, 2021

Possis Medical, Inc.
Mark Stenoien
Manager, Clinical & Regulatory Affairs
9055 Evergreen Blvd., N.w.
Minneapolis, Minnesota 55433-8003

Re: K040013
Trade/Device Name: AngioJet Xpeedior 120 Catheter And AngioJet Power Pulse Spray Ancillary Kit
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ, KRA

Dear Mark Stenoien:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 18, 2004. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.10.08 10:23:31 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 2004

Possis Medical, Inc.
c/o Mr. Mark Stenoien
Manager, Clinical and Regulatory Affairs
9055 Evergreen Boulevard NW
Minneapolis, MN 55433-8003

Re: K040013
Trade Name: AngioJet Xpeedior 120 Catheter and AngioJet Power Pulse Spray Ancillary Kit
Regulation Numbers: 21 CFR 870.5150, 870.1210
Regulation Names: Embolectomy Catheter, Continuous Flush Catheter
Regulatory Class: II (two)
Product Codes: DXE, KRA
Dated: March 31, 2004
Received: April 01, 2004

Dear Mr. Stenoien:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Lachman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K040013**

Device Name: **AngioJet Xpeedior 120 Catheter, and**
AngioJet Power Pulse Spray Ancillary Kit

Indications For Use:

1. The AngioJet Xpeedior 120 Catheter is intended for use with the AngioJet System in breaking apart and removing thrombus from infrainguinal peripheral arteries ≥3.0 mm in diameter.

2. The AngioJet Power Pulse Spray Ancillary Kit is intended for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system using the Xpeedior 120 Catheter and the AngioJet System.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmel

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040013

K040013

MAY 1 8 2004

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter:	Possis Medical, Inc. 9055 Evergreen Boulevard NW Minneapolis, MN 55433-8003 USA
Contact Person:	Mr. Mark Stenoien, Manager, Clinical & Regulatory Affairs 9055 Evergreen Boulevard NW Minneapolis, MN 55433-8003 USA Phone: (763) 780-4555 Fax: (763) 780-2227 Email: mark.stenoien@possis.com
Date Prepared:	31-Dec-2003
Trade Name:	The AngioJet Xpeedior 120 Catheter and the AngioJet Power Pulse Spray Ancillary Kit
Classification Name and Number:	AngioJet Xpeedior 120 Catheter is a class II device per 21 CFR 870.5150 for peripheral use and the Power Pulse Spray Ancillary Kit is a class II devices as defined by 21 CFR 870.1210.
Product Code:	AngioJet Xpeedior 120 Catheter product code is DXE. AngioJet Power Pulse Spray Ancillary Kit product code is 74 KRA.
Predicate Device(s):	The AngioJet 120 Catheter is substantially equivalent to the devices listed below: • The AngioJet LF140 Catheter (K972610) • The AngioJet Xpeedior 60 Catheter (K993564). The AngioJet Power Pulse Spray Ancillary Kit is substantially equivalent to: • AngioDynamics Power Pulsed Spray Infusion System (K905447 and K951509) • B.Braun Universal Spike Adaptor Y-Set (K780551).
Device Description:	The AngioJet Xpeedior 120 Catheter is a single-use component of the AngioJet Rheolytic Thrombectomy System. The AngioJet System uses high velocity saline jets for percutaneous break-up and removal of thrombus. The 6 FR Catheter has a tapered flexible polymeric tip, and a large outflow lumen for guide wire passage and removal of thrombus debris. A small second lumen contained within the large outflow lumen supplies pressurized saline to the Catheter tip. The Catheter is designed to track over a 0.305" guide wire and through a guide catheter or sheath having an inner diameter of 0.086" or larger, with sufficient clearance to allow manual contrast injection, if desired. The Catheter connects to the AngioJet Pump Set and the multiple-use AngioJet Drive Unit (each packaged separately), which are necessary for operation of the AngioJet System. The AngioJet Power Pulse Spray Ancillary Kit enables the AngioJet Xpeedior 120 Catheter to deliver a pulsed infusion of a physician-specified fluid to a local treatment area during a peripheral

	intervention. The Ancillary Kit also enables the Catheter to convert easily back to conventional AngioJet thrombectomy procedure. The AngioJet Power Pulse Spray Ancillary Kit includes a Y-set that is comprised of two vented bag spikes bonded to PVC tubing with a clamp attached on each tube and a short, larger diameter section of PVC tubing bonded to a Y-junction. The Y-set is used to access the standard intravenous saline solution bag, used with AngioJet thrombectomy, and a second intravenous bag containing physician specified fluid. The tube clamps are used to control the flow of each fluid. A separate one-way stopcock is included in the kit. This stopcock is placed between the Xpeedior 120 Catheters' outflow port, located on the underside of Catheter manifold, and the outflow tubing. The Power Pulse Spray Ancillary Kit is an accessory that is to be used only with the AngioJet Rheolytic Thrombectomy System and Xpeedior 120 Catheter and will be packaged independent from the AngioJet System components (i.e. the Drive Unit, Pump Set, and Catheter.)
Intended Use:	The AngioJet Xpeedior 120 Catheter is intended for use with the AngioJet System in breaking apart and removing thrombus from infrainguinal peripheral arteries $\geq$3.0 mm in diameter. The AngioJet Power Pulse Spray Ancillary Kit is intended for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system using the Xpeedior 120 Catheter and the AngioJet System.
Functional and Safety Testing:	Representative samples of the device underwent bench testing, including but not limited to mechanical testing, biocompatibility, sterility, comparative testing, and animal testing to safety and effectiveness and to demonstrate appropriate functional and performance characteristics.
Conclusion:	Possis Medical, Inc. considers the Xpeedior 120 Catheter and the Power Pulse Spray Ancillary Kit to be substantially equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and principles of operation.